

TAB 5

K061256

AUG 02 2006

510(K) SUMMARY

Date of Submission	01 May 2006
Official Contact / Address of Manufacturing facility	Zita A. Yurko Manager, Regulatory Affairs Respironics Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 Phone: 724-387-4120 Fax: 724-387-4216 Zita.Yurko@Respironics.com
Proprietary Name	SmartMonitor 2PS
Common/Usual Name	Apnea Monitor / Vital Signs Monitor
Device Classification Name	Monitor, Apnea, Home Use / Monitor, Breathing Frequency / Oximeter
Classification Reference	21 CFR 868.2377, 21 CFR 868.2375, and 21 CFR 870.2700
Classification	Class II
Appropriate Classification Panel	Anesthesiology
Product Code	NPF, BZQ, and DQA
Predicate Devices	Respironics, Inc. SmartMonitor 2PS (K032403) CAS Medical Systems, Inc. 9303 Neonatal / Adult Vital Signs Monitor (K982776)
Reason for submission	Modified Indications for use and design

Substantial Equivalence

This premarket notification submission demonstrates that the SmartMonitor 2PS with expanded claims is substantially equivalent to the Respironics SmartMonitor 2PS (K032403) cleared for the infant patient population and CAS Medical Systems 9303 Neonatal / Adult Vital Signs Monitor (K982776) cleared for the adult, pediatric, and neonatal patient population.

The functionality of the design of the monitor was verified through the use of design verification testing. The safety of the design was assured by the completion of IEC 60601-1 and IEC 60601-1-2 testing. The Risk Traceability Matrix provided in the Risk Analysis assures that all hazards identified by the risk analysis are successfully mitigated.

This submission is seeking to extend the existing claims of the SmartMonitor 2PS to include adult and pediatric use.

Intended Use

The SmartMonitor 2PS is intended for use in the continuous monitoring of respiration, heart rate and SpO₂ levels of infant, pediatric, and adult patients. It detects and alarms for periods of high or low heart rate, high or low breath rate, and high or low saturation. When used as an infant monitor it is intended for use in a home or hospital environment. For infants only, it monitors and alarms for central apneas. When used as a pediatric or adult monitor, it is intended for use in a hospital environment.

The SmartMonitor 2PSL is intended for use in the continuous monitoring of respiration, and heart rate of infant, pediatric, and adult patients. It detects and alarms for periods of high or low heart rate, and high or low breath rate. When used as an infant monitor it is intended for use in a home or hospital environment. For infants only, it monitors and alarms for central apneas. When used as a pediatric or adult monitor, it is intended for use in a hospital environment.

Device Description

The SmartMonitor 2PS is a microprocessor-based, software-controlled device intended for use as an infant apnea monitoring system or as an adult or pediatric vital signs monitoring system. The electro-mechanical design of the SmartMonitor 2PS is unchanged from the SmartMonitor 2PS (K032403) except that cleared ECG and oximetry sensor accessories have been selected for adult and pediatric use of the monitor.

Patient Usage:

The SmartMonitor 2PS is designed to analyze and record physiologic signals (ECG, respiration, SpO₂, and pulse rate) acquired from patients during sleep. Its primary function is to analyze the physiologic signals and generate visual and audible alarm indications upon detection of physiologic events such as central apnea (for infants), low breath rate (for adults and pediatrics), bradycardia, tachycardia, and high or low SpO₂. The portable design of the device facilitates its use in a hospital or in a home environment. The primary functions are unchanged from the existing design of the SmartMonitor 2PS (K032403). The only difference is that the implementation of these functions has been expanded to include the adult and pediatric patient populations.

System Description:

ECG and respiration signals are acquired via a single transducer set that is attached to the patient and directly connected to the monitor. The measurement method used to derive the respiration signal is transthoracic impedance. SpO₂ and plethysmographic pulse rate are acquired via an oximeter finger or foot sensor. The acquired physiologic signals are classified and stored for use at a later time. These system inputs are unchanged from the SmartMonitor 2PS (K032403), except that these features now include the adult and pediatric patient populations. No modifications to the SmartMonitor 2PS predicate firmware or hardware were needed to support the expanded intended use.

All of the following features are unchanged from the SmartMonitor 2PS (K032403):

- The SmartMonitor 2PS is a compact, lightweight unit. Two front panel connectors are provided for the patient sensor input. The sensor connectors and associated sensor plugs are individually keyed to prevent improper insertion.

- The SmartMonitor 2PS is approximately 7.4 inches wide, 10 inches deep and 2.5 inches high. It weighs approximately 2 pounds.
- The enclosure for the monitor is constructed of plastic injection molded materials, which are unchanged from K032403. Components and assemblies are securely mounted inside. The enclosure design is resistant to the entrance of liquids and other foreign materials.
- Locations for serial number plate and necessary user notes are provided at the bottom of the monitor.
- Accessories for the SmartMonitor 2PS include a patient cable, lead wires, ECG electrodes, a sensor belt to secure the sensors, and an oximeter sensor.
- Respiration Synergy-E Host PC Software is used to download or direct serial connect with the SmartMonitor 2PS for the purpose of downloading the monitor's previously stored data or retrieving the monitor's real time data.
- The functionality of the design of the monitor was verified through the use of design verification testing.
- The safety of the design was assured by IEC 60601-1 and IEC 60601-1-2 testing.
- The Risk Traceability Matrix provided the Risk Analysis assures that all hazards identified by the risk analysis are successfully mitigated.

(End of Tab.)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 02 2006

Respironics, Incorporated
C/O Ms. Zita A. Yurko
Manager, Regulatory Affairs
Sleep & Home Respiratory Group
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K061256

Trade/Device Name: Respironics SmartMonitor 2PS and 2PSL
Regulation Number: 21 CFR 868.2377
Regulation Name: Apnea Monitor
Regulatory Class: II
Product Code: NPF
Dated: July 5, 2006
Received: July 7, 2006

Dear Mr. Yurko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

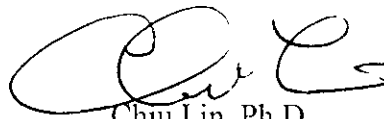
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K061256Device Name(s): Respironics SmartMonitor 2PS and 2PSL

The SmartMonitor 2PS is intended for use in the continuous monitoring of respiration, heart rate and SpO₂ levels of infant, pediatric, and adult patients. It detects and alarms for periods of high or low heart rate, high or low breath rate, and high or low saturation. When used as an infant monitor it is intended for use in a home or hospital environment. For infants only, it monitors and alarms for central apneas. When used as a pediatric or adult monitor, it is intended for use in a hospital environment.

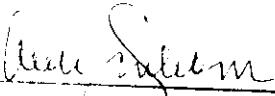
The SmartMonitor 2PSL is intended for use in the continuous monitoring of respiration, and heart rate of infant, pediatric, and adult patients. It detects and alarms for periods of high or low heart rate, and high or low breath rate. When used as an infant monitor it is intended for use in a home or hospital environment. For infants only, it monitors and alarms for central apneas. When used as a pediatric or adult monitor, it is intended for use in a hospital environment.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)Prescription Use XXXXX
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)



Authorized Signatory
Department of Anesthesiology, General Hospital,
Drug Control, Dental Devices
Device Number: K061256